PATENT CASE CV01492K

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:
T. Kosoglou et al.

Examiner: To Be Assigned

Group Art Unit: 1743

For:
COMBINATIONS OF STEROL ABSORPTION INHIBITOR(S) WITH BLOOD MODIFIERS FOR TREATING VASCULAR CONDITIONS

Attorney Docket No.: CV01492K

Serial No.: **10/056,680**

Filed: **January 25, 2002**

Assistant Commissioner of Patents
Washington, D.C. 20231

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Sir:

Applicants respectfully request that the following be considered and made of record, as well as the documents listed on the accompanying PTO Form 1449.

A research study was initiated on April 17, 1997 in the United States in which patients were administered capsules of the formulations of Exhibits A, B or C. Copies of the formulation Exhibits A, B and C and the informed consent form for the study (Exhibit 1) are submitted herewith for the Examiner's consideration.

A research study was initiated on October 21, 1997 in the United States in which patients were administered tablets of the formulations of Exhibits D or E or capsules of formulation of Exhibit C. Copies of the formulation Exhibits C, D and E and the informed consent for the study (Exhibit 2) are submitted herewith for the Examiner's consideration.

A research study was initiated on November 5, 1998 in the United States in which patients were administered tablets of formulations of Exhibits D, F, G or H. Copies of the formulation Exhibits D, F, G and H and the informed consent for the study (Exhibit 3) are submitted herewith for the Examiner's consideration.

A research study was initiated on April 20, 1999 in the United States in which patients were administered tablets of the formulation of Exhibit D, optionally in coadministration with digoxin. Copies of the formulation Exhibit D and the informed

consent for the study (Exhibit 4) are submitted herewith for the Examiner's consideration.

A research study was initiated on August 27, 1999 in the United States in which patients were administered tablets of the formulation of Exhibit D optionally in coadministration with Gemfibrozil 600mg tablets. Copies of the formulation Exhibit D and the informed consent for the study (Exhibit 5) are submitted herewith for the Examiner's consideration.

In the Informed Consents accompanying the above research studies, Schering's active pharmaceutical ingredient, i.e., ezetimibe, was identified as "SCH 58235" and as an "experimental drug which inhibits the absorption of cholesterol". It was not identified by its chemical name, generic name or by its chemical formula.

It is our belief that these studies do not constitute prior public uses. Nevertheless, this information is being disclosed in accordance with 37 C.F.R. Section 1.56 out of an abundance of caution.

The Commissioner is authorized to charge Deposit Account No. 19-0365 for any additional fees deemed necessary for consideration and entry of this Information Disclosure Statement into the file record.

I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope addressed to Assistant Commissioner for Patents, Washington D.C., 20231 on 4/28/03

Ann Marie Cannoni
Registered Representative

Signature 4/28/03 Date

Respectfully submitted

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FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE

INFORMATION DISCLOSURE STATEMENT BY APPLICANT

(Use several sheets if necessary)

ATTY. DOCKET NO.:	SERIAL NO.:
CV01492K	**10/056,680**
APPLICANT: **T. Kosoglou, et al.**	
FILING DATE: **01/25/2002**	GROUP: **1743**

OTHER DOCUMENTS *(Including Author, Title, Date, Pertinent Pages, Etc.)*

	AA	***Exhibit A:*** SCH 58235 Micronized (ezetimibe), Drug Formulation Development Summary
	AB	***Exhibit B:*** SCH 58235 (ezetimibe), Drug Formulation Development Summary
	AC	***Exhibit C:*** SCH 58235 (ezetimibe), Drug Formulation Development Summary
	AD	***Exhibit D:*** SCH 58235 (ezetimibe), Drug Formulation Development Summary
	AE	***Exhibit E:*** SCH 58235 (ezetimibe), Drug Formulation Development Summary
	AF	***Exhibit F:*** SCH 58235 (ezetimibe), Drug Formulation Development Summary
	AG	***Exhibit G:*** SCH 58235 (ezetimibe), Drug Formulation Development Summary
	AH	***Exhibit H:*** SCH 58235 (ezetimibe), Drug Formulation Development Summary
	AI	***Exhibit 1:*** Master Sheet for the SCH 58235 and Lovastatin Research Study, *Schering-Plough Research Institute* (Protocol No. C906-411), page 1576-1585
	AJ	***Exhibit 2:*** Medical Research Study #1055/97, SCH 58235: Bioavailability of Single Oral Doses of Two Prototype Tablet Formulations and the Reference Capsule Formulation of SCH 58235 in Normal Male Volunteers: A Four Way Crossover Study #C97-221-01, Informed Consent, *Peninsular Testing Corporation*, page 106-112
	AK	***Exhibit 3:*** Consent Form to Participate in a Research Study, "A Phase II Double Blind Dose Response Investigation of Efficacy and Safety of Four Doses of SCH 58235 Compared to Placebo in Subjects with Primary Hypercholesterolemia," *Schering-Plough Research Institute* (Protocol No. C98-010), page 1558-1566
	AL	***Exhibit 4:*** Medical Research Study #1096/99, SCH 58235: Pharmacokinetic Pharmacodynamic Drug Interaction Study with Digoxin in Healthy Volunteers #C98-114, Informed Consent, *Peninsular Testing Corporation*, page 124-130
	AM	***Exhibit 5:*** Informed Consent, "SCH 58235: Assessment of Multiple-Dose Drug Interaction Between 58235 and Gemfibrozil in Healthy Volunteers," *Schering-Plough Research Institute*, page 1-8

EXAMINER	DATE CONSIDERED

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.